Abbreviated 510(k)
Rhausler Plage Anterior Cervical Fusion System

Section 5: 510(k) Summary

Assigned 510(k) number:	K111272
Company:	Rhausler Inc. 837 Industrial Road, Unit E San Carlos, CA 94070 USA Phone: 650-631-4515 Fax: 650-631-4555
Contact:	Barbara DeBiase Phone: 303-537-3311 Email: barbdebiase@mac.com
Date Prepared:	November 28, 2011
Proprietary Names:	Rhausler Plage™ Anterior Cervical Fusion System
Classification Name:	Intervertebral body fusion device
Classification:	21 CFR 888.3080, Class II, Product Code ODP
Predicate Devices:	K071833 Mosaic™ by Spinal Elements Inc. K092521 Zuma-C™ by Seaspine Inc.
Device Description:	The Rhausler Plage Anterior Cervical Fusion System consists of titanium plage (one piece cervical plate and cage) implants, titanium locking bone screw implants, and instruments. Implants are provided in a variety of dimensions. The Plage is designed with slots for bone screw placement. The Plage center lower cage portion is open to allow the opening to be filled with autogenous bone. The Plage System is provided nonsterile.
Intended Use:	Intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone. This device is to be used in patients who have had at least 6 weeks of nonoperative treatment.
Technological Comparison to Predicate Device:	The Rhausler Plage Anterior Cervical Fusion System is similar to the predicate device. Both are intervertebral body fusion devices

that attach to the anterior portion of the cervical spine during the development of spinal fusion. Additionally, both use the same fundamental scientific technology, principle of operation, and materials. Performance test results confirm that design differences do not pose new issues of safety or effectiveness.

Performance Testing: Mechanical testing has been performed on the Rhausler Plage Anterior Cervical Fusion System per ASTM F2077 (static and dynamic compression and torsion). Subsidence testing has been performed per ASTM F2267, and wear testing has been performed per ASTM F1877. Results of performance testing are substantially equivalent to the predicate devices.

Conclusion: Based upon the design, technology, performance, and intended use, the Rhausler Plage Anterior Cervical Fusion System is substantially equivalent to the predicate device currently marketed under the Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 29 2011

Rhausler, Inc.
% Ms. Barbara DeBiase
837 Industrial Road, Unit E
San Carlos, California 94070

Re: K111272
Trade/Device Name: Rhausler Plage™ Anterior Cervical Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: October 10, 2011
Received: October 11, 2011

Dear Ms. DeBiase:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k111272

Device Name: Rhausler Plage™ Anterior Cervical Fusion System

Indications for Use:

Intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone. This device is to be used in patients who have had at least 6 weeks of nonoperative treatment.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111272